

Message Text

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SUBJECT: US-EC MEETING ON TOXIC SUBSTANCES: JANUARY 18-
20, 1978

REF: 77 BRUSSELS 13888

1. SUMMARY: THE SECOND INFORMATIONAL US-EC MEETING ON
TSCA WAS HELD IN BRUSSELS JANUARY 18-20. THE PURPOSE OF
THE MEETING WAS TO EXCHANGE VIEWS ON THE US IMPLE-
MENTATION OF TSCA AND THE EC PROGRAM ON THE VI AMENDMENT
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TO THE 1967 DANGEROUS SUBSTANCE DIRECTIVE. THE APPROXI-
MATELY 80 PARTICIPANTS ON THE EC SIDE REPRESENTED THE
EC COMMISSION, THE NINE MEMBER STATES AND THE EUROPEAN
FEDERATION OF CHEMICAL INDUSTRIES. THE SEVEN US PARTI-
CIPANTS REPRESENTED EPA, FDA, COMMERCE AND STATE. EXCHANGES
AT THE TECHNICAL LEVELS WERE HELPFUL IN CONTRIBUTING
TOWARD THE UNDERSTANDING OF THE RESPECTIVE PROGRAMS ON
TOXIC SUBSTANCES. DISCUSSIONS ON THE ADMINISTRATION OF
TOXIC SUBSTANCES CONTROL SUGGESTED MANY AREAS FOR
POTENTIAL HARMONIZATION AND EXCHANGE OF INFORMATION. A

NUMBER OF THESE AREAS, HOWEVER, SUCH AS AGREEMENTS ON QUALITY ASSURANCE OF DATA AND ASSESSMENT METHODOLOGY, WILL REQUIRE POLICY DECISIONS. EC CHAIRMAN CARPENTEIER SAID IN HIS CONCLUSION, THAT "WE NOW HAVE A BASE FROM WHICH TO PROCEED TO MORE FORMAL NEGOTIATION." COOPERATION BETWEEN THE US AND THE EC ON CONTROL OF TOXIC SUBSTANCES, ESPECIALLY HARMONIZATION OF TSCA PREMANUFACTURING NOTIFICATION AND EC PREMARKETING NOTIFICATION PROCEDURES, IS NECESSARY TO ENSURE THAT NATIONAL LEGISLATION ON THESE MATTERS AVOID BECOMING OR BEING INTERPRETED AS NON-TARIFF BARRIERS TO TRADE IN NEW CHEMICALS. END SUMMARY

2. THE MEETING OPENED IN PLENARY SESSION. CARPENTIER, HEAD OF THE EC ENVIRONMENT AND CONSUMER PROTECTION SERVICE (ECPS), CHAIRED THE SESSION. WALLIN, (EPA) READ AN OPENING STATEMENT WHICH DETAILED PROGRESS ON THE TOXIC SUBSTANCES CONTROL ACT (TSCA) SINCE THE OCTOBER MEETING. JOHNSON (ECPS) EXPLAINED THE EC PROGRESS ON THE SIXTH AMENDMENT TO THE 1967 DIRECTIVE ON DANGEROUS SUBSTANCES. THE MEETING THEN BROKE INTO THREE WORKING GROUPS FOR THE NEXT DAY AND A HALF. THE THREE WORKING GROUPS DISCUSSED RESPECTIVELY: EXAMINATION AND EVALUATION OF TOXICITY TESTING; EXAMINATION AND EVALUATION OF UNCLASSIFIED

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ECOTOXICITY TESTING; AND ADMINISTRATIVE ASPECTS OF TOXIC SUBSTANCES CONTROL. SUMMARIES FOLLOW:

GROUP I - EXAMINATION AND EVALUATION OF TOXICOLOGICAL TESTING

(CHAIRMAN - BERLIN (EC), US MEMBERS - PAYNTER (COMMERCE) AND MORRIS (EPA)). THE OBJECT OF THE MEETING WAS TO CONTINUE THE DISCUSSION BEGUN IN THE OCTOBER MEETING ON ACUTE TOXICITY AND TO EXPAND THE DISCUSSION TO INCLUDE OTHER ASPECTS OF TOXICOLOGY. IT WAS AGREED THAT ATTENTION SHOULD BE FOCUSED ON THE BASE SET DATA ASSOCIATED WITH THE VITH AMENDMENT. THIS WAS DONE WITH A VIEW TO IDENTIFYING AREAS FOR POTENTIAL HARMONIZATION BETWEEN THE EC PREMARKETING NOTIFICATION AND THE PREMANUFACTURING NOTIFICATION SECTION OF TSCA.

IN COMPARING THE REQUIREMENTS OF THE VITH AMENDMENT WITH THOSE OF THE FIRST LEVEL OF THE EPA HIERARCHICAL TESTING SCHEME, IT WAS EVIDENT THAT THERE WERE CORRELATIONS FOR: SINGLE ADMINISTRATION TOXICITY; REPEATED ADMINISTRATION TOXICITY FOR LESS THAN THIRTY DAYS; AND SHORT TERM TESTS FOR GENOTOXICITY AND ONCOGENICITY.

THE US REPRESENTATIVES EXPLAINED THAT THE HIERARCHICAL TESTING SCHEME WAS STILL UNDER DISCUSSION AND THAT

NO FIRM DECISIONS HAD YET BEEN MADE. ONE SUCH PARAMETER WHICH WAS STILL UNDER CONSIDERATION CONCERNED THE VOLUME OF CHEMICAL REQUIRED TO PROCEED TO LEVEL 2, WHICH CURRENTLY STANDS AT MORE THAN ONE METRIC TON PER YEAR (NON CUMULATIVE). THE COMMISSION ECHOED THIS VIEW AND STATED THAT ALTHOUGH 100 KG FOR RESEARCH PURPOSES AND ONE TON FOR DEVELOPMENT PURPOSES WERE CONSIDERED THE TRIGGER POINT FOR THE BASE SET DATA, THESE FIGURES WERE TENTATIVE AND COULD BE MODIFIED.
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ANOTHER ASPECT WHICH RESULTED IN CONSIDERABLE DISCUSSION CONCERNED THE CONCEPT OF HIGH HAZARD POTENTIAL. IN VIEW OF THE CONSIDERABLE INTEREST IN THIS CONCEPT, THE US AGREED TO PUT FORWARD A TENTATIVE DEFINITION, WHICH COVERED THE CONCEPT AS THEY WISHED IT TO BE CONSIDERED IN THE TENTATIVE TESTING SCHEME DISTRIBUTED AT THE MEETING.

EPA ALSO STATED THAT LEVEL TWO "PRE-CHRONIC TOXICOLOGY" AND LEVEL THREE "LONG-TERM BIOASSAY, ONCOGENICITY" IN THE HEIRARCHICAL TESTING SCHEME MIGHT BE FUSED TOGETHER, BUT NO DECISION HAD YET BEEN TAKEN IN THIS REGARD.

IN DISCUSSING ACUTE AND SHORT TERM TOXICITY TESTS, THE EC INDICATED THAT A NUMBER OF INTERCOMPARISON STUDIES HAD BEEN INITIATED AND THAT IN SOME A SECOND STAGE WOULD BEGIN IN THE NEAR FUTURE. THE US INDICATED A WILLINGNESS TO PARTICIPATE IN SUCH A VENTURE.

GROUP II - EXAMINATION AND EVALUATION OF ECOTOXICOLOGICAL

TESTS

(CHAIRMAN - SMEETS (EC), US MEMBERS - STERN (EPA) AND ASHER (FDA)). GROUP II REACHED GENERAL CONSENSUS ON THE NEED FOR THE FOLLOWING PHYSICO-CHEMICAL TESTS: PH STABILITY, IONIZATION CONSTANT, BIODEGRADABILITY, LIPID SOLUBILITY, FISH TEST LC-50, DAPHNIA, ALGAE AND BIO-ACCUMULATION TESTS. THE DISCUSSION OF THE SPECIFIC PARAMETERS OF EACH TEST SHOWED A NEED FOR FURTHER INVESTIGATION AND DISCUSSION BEFORE CONSENSUS COULD BE REACHED.

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DIFFERENT VIEWS WERE EXPRESSED REGARDING THE PARAMETERS AND NECESSITY OF ABSORPTION-DESORPTION TESTS, IMPORTANCE OF DEGRADATION PRODUCTS AND METABOLITES AND THE USE OF TERRESTRIAL ECOSYSTEMS. THE US MEMBERS INDICATED THAT THE US WAS CONSIDERING THESE TESTS, WHILE

VARIOUS EC MEMBERS QUESTIONED THE NEED FOR SOME, AND INDICATED THAT OTHERS HAD NOT BEEN CONSIDERED. THE GROUP AGREED THAT PARTICLE SIZE DISTRIBUTION PARAMETERS FOR THE PRESENT SHOULD NOT BE MANDATORY EXCEPT IN SPECIFIC INSTANCES WHERE AS AN INTRINSIC PROPERTY OF THE CHEMICAL. IT COULD BE USED AS AN INDICATOR OF POSSIBLE TOXICITY.

THE GROUP ALSO DISCUSSED THE RESULTS OF THE BERLIN SEMINAR ON ECOTOXICITY.

GROUP III: ADMINISTRATIVE ASPECTS OF TOXIC

SUBSTANCES CONTROL

(CHAIRMAN - JOHNSON, (EC), US MEMBERS - WALLEN (EPA), FULLER (EPA), BLANCHARD (STATE)).

DISCUSSIONS BETWEEN THE U.S. AND EC WERE HELD ON THE FOLLOWING TOPICS:

(A) MUTUAL RECOGNITION OF THE BASIC DOSSIER.

THE EC DESCRIBED THE CURRENT STATE OF WORK WITHIN THE EC REGARDING THE ELABORATION OF A BASE-SET OF INFORMATION FOR THE PREMARKETING NOTIFICATION (BASIC DOSSIER) CALLED FOR IN THE VITH AMENDMENT. BROAD AGREEMENT HAD BEEN REACHED WITHIN THE EC WITH REGARD TO THE BASIC DOSSIER ON THE IDENTITY OF SUBSTANCES TO BE NOTIFIED, DATA ON UTILIZATION, PHYSICO-CHEMICAL PROPERTIES AND ON TESTS UNCLASSIFIED

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CONCERNING ACUTE TOXICITY, SUB-ACUTE TOXICITY, MUTAGENICITY, ECOTOXICITY (EFFECTS ON TWO REPRESENTATIVE SPECIES) AND BIODEGRADABILITY. THIS WOULD APPLY TO ALL NEW SUBSTANCES WITH THE EXCEPTION OF SUBSTANCES MEANT FOR RESEARCH AND DEVELOPMENT (UP TO ONE TON). THE US DELEGATION EXPLAINED THAT THEY WERE NOW IN THE PROCESS OF ATTEMPTING TO WORK OUT A SIMILAR BASIC DOSSIER FOR THE PURPOSE OF THEIR PREMANUFACTURE NOTIFICATION SCHEME COVERING NEW CHEMICALS.

HARMONIZATION OF THE ESSENTIAL ELEMENTS OF THE BASIC DOSSIER MIGHT IN THE LONG RUN HELP THE COMMUNITY AND THE UNITED STATES MOVE IN THE DIRECTION OF MUTUAL RECOGNITION OF EACH OTHER'S NOTIFICATION PROCEDURES ON NEW SUBSTANCES. BOTH SIDES EXPRESSED THE FEELING THAT ALL POSSIBLE STEPS SHOULD BE TAKEN TO AVOID OBSTACLES TO THE INTERNATIONAL TRADE IN CHEMICALS.

(B) ASSESSMENT PROCEDURES:

WHILE IT WAS RECOGNIZED THAT THE ASSESSMENT OR RISKS

WOULD ALWAYS RETAIN CERTAIN SUBJECTIVE ASPECTS (E.G., THE CHARACTERISTICS OF THE ENVIRONMENT OR OF THE EXPOSED POPULATION AND POLITICAL PRIORITIES AS FAR AS CONTROL STRATEGIES ARE CONCERNED, DIFFER FROM ONE COUNTRY TO ANOTHER), THERE WAS NEVERTHELESS A CASE FOR ARRIVING AT A DEGREE OF AGREEMENT ON:

. -- METHODOLOGY OF THE TESTS THEMSELVES:

IT WAS HOPED THAT THE EC COUNCIL WOULD ADOPT THE VITH AMENDMENT AT AN EARLY DATE LEAVING FURTHER DETAILS TO BE WORKED OUT BY EXPERTS, TAKING INTO ACCOUNT WORK ON METHODOLOGY BEING CONDUCTED ELSEWHERE, E.G., WITHIN THE FRAMEWORK OF OECD. BUT HERE, TOO, THERE WAS A UNCLASSIFIED

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NEED FOR SPECIFIC U.S.-EC CONTACTS.

-- ACCREDITATION PROCEDURES:

THE U.S. DELEGATION DESCRIBED THE EXPERIENCES ASSOCIATED WITH "SUSPECT" DATA SUBMITTED TO THE GOVERNMENT FOR REGULATORY PURPOSES. THE RESULTANT DIFFICULTIES PRESENTED BOTH TO GOVERNMENTS IN DISCHARGING THEIR DUTIES IN PROTECTING PUBLIC HEALTH AND WELFARE AND TO INTERNATIONAL ORGANIZATIONS UTILIZING "SUSPECT" DATA FOR ESTABLISHING ALLOWABLE HUMAN EXPOSURE LEVELS WORLD-WIDE TO CHEMICALS IN THIS CATEGORY IS A DEFINITE PROBLEM THAT HAS TO BE CORRECTED. TWO APPROACHES TO SOLVING THIS PROBLEM WERE NOTED: (1) ACCREDITING DATA GENERATED BY LABORATORIES, AND (2) ACCREDITING LABORATORIES TO PRODUCE DATA.

(C) CONFIDENTIALITY:

THE U.S. DELEGATION COMMENTED ON ALREADY DISTRIBUTED DOCUMENTS RELATING TO CONFIDENTIALITY. THEY EXPLAINED THAT THE TSCA DID NOT PERMIT THE TOTALITY OF INFORMATION TO REMAIN CONFIDENTIAL. CONSIDERABLE INTEREST WAS EXPRESSED BY THE EC MEMBERS ABOUT THE EXTENT OF DATA COVERED BY CONFIDENTIALITY AND THE PROCEDURES TO BE EMPLOYED IN CARRYING OUT THIS RESPONSIBILITY.

(D) COST SHARING:

THERE IS A MAJOR DIFFERENCE BETWEEN THE TSCA PREMANUFACTURING NOTIFICATION AND THE EC PREMARKETING NOTIFICATION PROCEDURES. IN THE US, ONCE A CHEMICAL IS REGISTERED WITH TSCA, ALL MANUFACTURERS CAN THEN MARKET THE CHEMICAL. IN THE EC EACH NEW MANUFACTURER OF THE SAME CHEMICAL MUST SUBMIT A DOSSIER PRIOR TO MARKETING THE CHEMICAL. PROVISIONS FOR THE EQUITABLE SHARING OF UNCLASSIFIED

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COSTS ASSOCIATED WITH THE PREPARATION OF BASIC DOSSIERS WERE DISCUSSED WITHIN EACH FRAMEWORK.

(E) INVENTORY AND LISTS OF SUBSTANCES:

THE U.S. DELEGATION EXPLAINED THE NATURE OF THE INVENTORY IN THE TSCA. THE EMPHASIS WAS THE CONTROL OF EXISTING CHEMICAL SUBSTANCES. THE EMPHASIS IN THIS SECTION OF TSCA, NATURALLY LED TO A DIFFERENCE IN THE DEGREE OF IMPORTANCE ATTACHED TO THE EC INVENTORY ON NEW CHEMICALS ASSOCIATED WITH THE VITH AMENDMENT.

IN THE EVENT THAT THE EC WAS ABLE TO ELABORATE ITS OWN INVENTORY IN ORDER TO INCLUDE EXISTING CHEMICALS, CONSIDERATION SHOULD BE GIVEN TO SOME FORM OF RECIPROCITY OR HARMONIZATION WITH THE US INVENTORY.

(F) PRIORITY LISTING OF SUBSTANCES:

THE U.S. DELEGATION OUTLINED THE PROCEDURE CURRENTLY BEING DEVELOPED IN THE US FOR THE PRIORITY LISTING OF SUBSTANCES, IN PARTICULAR THE USE OF THE INTERAGENCY TESTING COMMITTEE. MENTION WAS ALSO MADE THAT THE COMMISSION WAS IN THE PROCESS OF ESTABLISHING A SCIENTIFIC COMMITTEE ON TOXICOLOGY AND ECOTOXICOLOGY TO ADVISE IT, AMONG OTHER THINGS, ON THE IDENTIFICATION OF PRIORITY SUBSTANCES FOR SCREENING OR FOR CONTROL. THERE WAS RECOGNITION OF THE NEED FOR COLLABORATION BETWEEN THE US AND THE EC AS FAR AS THE SELECTION OF PRIORITY SUBSTANCES FOR TESTING WAS CONCERNED AND POSSIBLY ALSO FOR CONTROL. ON THE EC SIDE IT WAS POINTED OUT THAT COMMUNITY LEGISLATION DID IN FACT EXIST REGARDING THE CONTROL OF EXISTING CHEMICAL SUBSTANCES, FOR EXAMPLE, THE SO-CALLED "LIMITATIONS" DIRECTIVE WHICH ALREADY UNCLASSIFIED

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REGULATED THE USE OF POLYCHLORINATED BIPHENYLS (PCB) AND VINYL CHLORIDE MONOMERS (VCM).

3. TOPICS RAISED BY THE COMMISSION WITH REGARD TO THE TSCA:

(A) POWER OF STATES TO IMPLEMENT CONTROL OVER TOXIC SUBSTANCES:

THE U.S. DELEGATION AGREED TO LOOK INTO THE POSSIBILITY OF INDIVIDUAL STATES TO IMPOSE MORE STRINGENT REQUIREMENTS THAN THOSE LAID DOWN IN THE FEDERAL LEGISLATION. A REPLY TO THE COMMISSION WOULD BE PREPARED.

(B) CONTROL OF IMPURITIES IN THE SUBSTANCES:

MIXTURES - NEW CHEMICAL SUBSTANCES CONTAINED IN MIXTURES WILL BE SUBJECT TO PREMANUFACTURE NOTIFICATION REQUIREMENTS. THEREFORE THE IMPORTER MAY REPORT CHEMICAL SUBSTANCES IN MIXTURES ON THE INVENTORY.

ARTICLES - CURRENTLY, IMPORTERS OF CHEMICAL SUBSTANCES AS PART OF ARTICLES ARE NOT REQUIRED TO REPORT FOR THE INVENTORY. EPA WILL CAREFULLY CONSIDER THE ECONOMIC AND INTERNATIONAL RAMIFICATIONS THAT MAY BE APPLIED TO CHEMICAL SUBSTANCES IN ARTICLES. IF, ON REEVALUATION, THESE REGULATIONS SHOULD APPLY, A PROPOSED NOTICE WILL BE PUBLISHED FOR FURTHER PUBLIC COMMENT. CHEMICAL SUBSTANCES IN ARTICLES MAY BE REPORTED ON THE INVENTORY.

(C) SMALL BUSINESSES:

THE U.S. DELEGATION EXPLAINED THAT SMALL BUSINESSES ARE NOT EXCLUDED FROM THE REQUIREMENT OF REPORTING FOR THE INVENTORY. THE EXCLUSIONS RELATE ONLY TO SITE AND VOLUME, NOT SIZE OF THE BUSINESS.

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(D) REPORTING FORMS:

A NUMBER OF REPRESENTATIVES STRESSED THE NEED TO HAVE AN ADEQUATE AND TIMELY SUPPLY OF REPORTING FORMS. THE U.S. DELEGATION TOOK NOTE OF THIS REQUEST, SINCE FORMS ARE CODED AND ORIGINALS MUST BE SUBMITTED TO EPA. IN ORDER TO ENSURE THAT ALL FOREIGN MANUFACTURERS RECEIVE SUFFICIENT FORMS IN TIME TO COMPLY WITH THE MAY DEADLINE FOR INVENTORY REPORTING, AN EPA MEETING WITH THE AMERICAN IMPORTERS ASSOCIATION AND FOREIGN EMBASSY REPRESENTATIVES WAS SUGGESTED.

4. A PLENARY SESSION WAS HELD DURING THE AFTERNOON OF JANUARY 20 IN WHICH THE CHAIRMAN OF EACH OF THE THREE GROUPS PRESENTED SUMMARIES OF THEIR MEETINGS. CARPENTIER EXPRESSED GREAT SATISFACTION WITH THE RESULTS AND STATED THAT HE BELIEVED A BASE HAD BEEN ESTABLISHED WHICH WOULD PERMIT MORE FORMAL DISCUSSIONS WHICH COULD LEAD TO A FORMAL AGREEMENT. HE SAID THAT ON THE BASIS OF THE RESULTS OF THIS MEETING THE COMMISSION WOULD ASK FOR A MANDATE TO ALLOW FURTHER WORK ON SCIENTIFIC COOPERATION. PARALLEL WORK BEING DONE IN THE OECD AND THE APRIL STOCKHOLM MEETING WILL ALSO BE CONTINUED. IN THIS SUMMATION OF THE RESULTS, CARPENTIER POINTED OUT THE NEED TO WORK OUT COMMON GUIDELINES FOR METHODOLOGY AND ACCREDITATION. IN THE AREA OF US/EC COOPERATION, THE KEY WORD IS QUALITY ASSURANCE. HE ALSO NOTED THAT THERE ARE JURIDICAL IMPLICATIONS IN MOVING TOWARDS

MUTUAL RECOGNITION OF THE BASIC DOSSIER OR OF THE NOTIFICATION WHICH WOULD REQUIRE SPECIAL AGREEMENT BETWEEN THE US AND EC.

5. COMMENT: WHILE NO FINAL AGREEMENTS WERE REACHED
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THE SIMILARITY OF SCIENTIFIC EXPERT OPINION WAS EVIDENT. THE BASIC ACCORD BETWEEN THE US AND THE EC ON MANY OF THE TECHNICAL ASPECTS OF CONTROL OF TOXIC SUBSTANCES SHOWS THAT, IF THE US DESIRES IT, HARMONIZATION OF LEGISLATION BETWEEN THE US AND EC COULD PROBABLY BE ACCOMPLISHED. THE OPEN EXCHANGE OF INFORMATION WILL IN ANY EVENT BE USEFUL IN THE BROADER CONTEXT OF THE OECD WORKING GROUPS. WITHIN THE NEXT EIGHT MONTHS EPA WILL BE DEVELOPING PRE-MANUFACTURING NOTIFICATION PROCEDURES. THE EC CONCURRENTLY WILL BE WORKING ON PRE-MARKET NOTIFICATION PROCEDURES. WE BELIEVE IT IS IMPORTANT THAT EXTENSIVE HARMONIZATION OF THESE PROCEDURES BE EFFECTED IN ORDER TO ENSURE THAT ANY TECHNICAL BARRIERS TO TRADE IN NEW CHEMICALS BETWEEN THE US AND EC WHICH CAN BE AVOIDED, ARE. DURING THE FIRST 6 MONTHS OF 1977 THE US EXPORTED OVER \$1.5 BILLION OF CHEMICALS TO THE EC AND IMPORTED \$1.1 BILLION FROM THE EC. FOR OECD COUNTRIES, EXPORTS TOTALED OVER \$3 BILLION AND IMPORTS, OVER \$2 BILLION. WE BELIEVE IT IS IN THE INTEREST OF THE US TO HARMONIZE LEGISLATION ON CONTROL OF TOXIC SUBSTANCES, BE IT ON AN INTERNATIONAL, OECD OR EC LEVEL. THE TWO MAJOR PROBLEM AREAS WHICH MUST NOW BE RESOLVED CONCERN AGREEMENTS ON QUALITY ASSURANCE OF DATA AND ASSESSMENT METHODOLOGY. THESE WILL REQUIRE POLICY DECISIONS DUE TO THE POLITICAL AND ECONOMIC PROBLEMS THEY RAISE. THE EC COMMISSION AND THE MISSION FEEL THAT THE EXPANSION OF THE US REPRESENTATION AT THIS MEETING TO INCLUDE FDA, COMMERCE AND STATE CONTRIBUTED GREATLY TO ITS SUCCESS, BY INTRODUCING A BROADER PERSPECTIVE. HINTON UNQUOTE VANCE

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